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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,611	07/01/2003	James E. Brewer	A03P1048	4743
36802	7590	05/06/2005	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/612,611	Applicant(s) BREWER ET AL.	
	Examiner Alyssa M Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/01/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-10, 12-16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin et al. (US 5,549,650). Bornzin et al. discloses a system and method directed toward a pacemaker that includes a processing system that receives signals indicative of cardiac mechanical activity from a cardiac wall motion sensor and uses the sensor signals to derive physiologic parameters which enable the pacemaker to provide hemodynamically optimal pacing therapy”(col. 4, lines 23-28). The processing system “processes the derived cardiac wall motion signals (i.e., cardiac wall velocity and displacement) to produce signals representative of stroke volume, cardiac contractility, pre-ejection period and ejection time”(col. 5, lines 1-5). The examiner considers “the pre-ejection period which may be determined based on cardiac wall velocity or acceleration signals and electrocardiogram” (col. 5, lines 57-59) to be a displacement based on sensed potential, since Bornzin et al. discloses the use of acceleration signals in conjunction with an electrocardiogram.

As to claims 4-5 and 9-10, Bornzin et al. discloses in col. 5 and 6, lines 53-67 and 1-5, the use of cardiac wall motion sensor signals to determine the pre-ejection period and ejection time by measuring the onset and termination of a cardiac

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contraction. The pre-ejection period is the time between stimulus--R-wave--and the beginning of mechanical contraction of the heart and the ejection time is the time between the onset of a cardiac contraction and the end of the contraction, or the time required for a "full" heart cavity, such as the left or right ventricle, to empty. According to Hole's Human Anatomy and Physiology {Reference U}, page 593, figure 15.16, the pre-ejection period and ejection period occur during ventricular systole or contraction of the ventricles. In addition, Hole's Human Anatomy and Physiology also teaches that atrial diastole occurs when ventricular contract (ventricular systole). Therefore, Bornzin et al. inherently teaches the determining tissue displacement during systole and diastole.

As to claims 12-14, the examiner considers the first displacement to be the maximum and the second displacement signal to be the minimum. In addition to teaching the determining tissue displacement during systole and diastole, Bornzin et al. also inherently teaches calculating the difference between the first and second displacement, since "stroke volume may be determined by calculating the difference between the minimum and maximum displacement, as shown by difference 310, based on cardiac wall motion sensor signals, for an individual heartbeat"(col. 12, lines 20-23).

As to claims 15-16 and 18-19, "the second integral of the cardiac acceleration signals (i.e., cardiac wall displacement, as described above in connection with FIGS. 2 and 3) is used to provide stroke volume in a highly accurate and reliable manner so that an implantable cardiac stimulating device may rely on the stroke volume data during all phases of the delivery of pacing pulses"(col. 12, lines 24-29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. (US 5,549,650). Bornzin et al. discloses the claimed invention except for the second lead in the right ventricle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the leads as taught by Bornzin et al. with a lead to the right ventricle since it was known in the art to place leads in the right ventricle in order pace the heart.
2. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. (US 5,549,650). Bornzin et al. discloses the claimed invention except for the calculating of survival risk based on left ventricular ejection fraction and the activity test parameter. Zugck et al. teaches that it is known to utilize a 6-min walking test to determine Heart Failure Survival Score (HFSS) as set forth in "Risk stratification in middle -aged patients with congestive heart failure: prospective comparison of the Heart Failure Survival Score (HFSS) and a simplified two-variable model". It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the activity calculations as taught by Bornzin et al. with the 6-min walking test to determine Heart Failure Survival Score (HFSS) as taught by Zugck et al., in order to assess the patients cardiac condition.

3. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. (US 5,549,650). Bornzin et al. discloses the claimed invention except for the fractional shortening. Schussheim et al. teaches that it is known to utilize fractional shortening as set forth in "Midwall fractional shortening is an independent predictor of left ventricular diastolic dysfunction in asymptomatic patients with systemic hypertension". It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the cardiac calculations as taught by Bornzin et al. with fractional shortening as taught by Schussheim et al., in order to assess the patients cardiac health and to identify patients at risk for hypertension.

Specification

1. The disclosure is objected to because of the following informalities: through out the specification "resistivity" is followed by a box character, presumably in place of a character that did not transfer. The examiner believes this character might be rho, based on equation 6 on page 23. Appropriate correction is required.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Mouchawar et al. (US 5,480,412) discloses a system and method for deriving hemodynamic signals from a cardiac wall motion sensor.
2. Mouchawar et al. (US 6,009,349) discloses a system and method for deriving hemodynamic signals from a cardiac wall motion sensor.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M. Alter

Alyssa M Alter
Examiner
Art Unit 3762 *tw*

[Signature]
JEFFREY R. JASTRZAB
PRIMARY EXAMINER

5/2/05